DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

Telephone: 425-486-8788
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March 13, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-33

Joanne R. Wysong, Owner
Green Mountain Smoked Salmon
2050 Cloverdale Road
Kalama, Washington 98625

WARNING LETTER

Dear Ms. Wysong:

We inspected your firm, located at 2050 Cloverdale Road, Kalama, Washington, on November 15, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123-Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your smoked salmon spread to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.16 and 21 CFR 123.6(b) and (c)(1). Your firm's HACCP plan for smoked salmon spread does not list the food safety hazard of *Clostridium botulinum (C. botulinum)*. This deviation was previously brought to your attention in our letter of April 26, 1999.

2. You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). Your temperature monitoring logs for the storage critical control point for control of pathogen growth in smoked salmon spread has no actual temperature values recorded for the month of February 1999. Instead, you have drawn a line down a column marked yes, indicating the critical limit was met. Moreover, the continuity of the line indicates this record was not made concurrent with actual daily observations.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, in order to comply with 21 CFR 123.7(b). Your corrective action plan for smoked salmon spread at each of your critical control points to control pathogen growth does not include corrections for both the product and the process. An appropriate corrective action must ensure that any unacceptable product does not enter commerce, and the cause of the deviation must be addressed to prevent the recurrence of the same deviation.

4. You must verify that your HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.8(a). Your firm did not verify the adequacy of the critical limit of 140 degrees Fahrenheit for 30 minutes for smoked salmon spread at the hot smoke critical control point to control pathogen growth, including *C. botulinum*. Monitoring the temperature of the smokehouse, instead of the internal temperature of the product, does not ensure adequate control of pathogen growth, including *C. botulinum*. This deviation was brought to your attention in our letters of April 26, 1999, and September 24, 1999.

5. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan lists a critical limit of salt brine concentration in excess of [redacted]% at the brining critical control point. Your HACCP plan for smoked salmon does not identify the specific critical limits for brine time and brine strength that must be met in order to achieve a minimum water phase salt level of 3.5% in your finished product. Further, your HACCP plan does not include in-process or finished product testing as required by 21 CFR 123.8(a) as a means of verification at the brining step to ensure your product is achieving a 3.5% water phase salt level.

6. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for smoked salmon spread lists a critical limit, "keep temperature below 45°F", at the storage/distribution critical control point which is not adequate to control pathogen growth (specifically *C. botulinum*). The minimum temperature for growth of *C. botulinum* type E and nonproteolytic type B and F is 38 degrees Fahrenheit. As the shelf life of refrigerated food is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all your products are in compliance with the applicable statutes enforced by the FDA. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

We are in receipt of your undated response letter (received November 19, 1999) to the recent inspection of your firm. Unfortunately, your response is incomplete and inadequate.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. Please include in your response the following documentation: revised HACCP plan; calibration records for all process monitoring instruments; laboratory results for percent water phase salt analysis of the finished product (smoked salmon spread); scientific support for the brining and smoking process. This information was previously requested in our letters to you on April 26, 1999 and September 24, 1999. You may include any other useful information you feel that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2nd Avenue, Suite 2400, Seattle, Washington 98104. If you have any questions regarding any issue in this letter, please contact Robert Wesley at 206/553-7001, extension 57.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR 123
Section 402 of the Federal Food, Drug and Cosmetic Act

Cc: WSDA with disclosure statement